

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/863,786	PALMGREN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deborah A. Davis	1641	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to An appeal brief filed 10-28-05.
2. ☒ The allowed claim(s) is/are 1-6 and 8-12 (renumbered 1-11).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                     | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input type="checkbox"/> Other _____.  |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Ji on January 26, 2006.

IN THE CLAIMS:

***Claims 1-6 and 8-12 have been replaced as follows:***

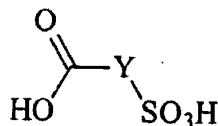
***Cancel claims 7 and 13-20***

Claim 1 (currently amended) A method of identifying a polypeptide, which method comprises the steps of

- (a) derivatizing, in an aqueous solution, the N-terminus of the polypeptide, or the N-termini of one or more peptides of the polypeptide, with at least one acidic reagent containing a ~~sulfonyl~~-sulfo moiety coupled to an ester moiety to provide one or more peptide derivatives, which reagent exhibits a half-life in aqueous solution of not less than 10 minutes at room temperature, to prepare one or more derivatives;
- (b) analyzing at least one said derivative using a mass spectrometric technique to provide a fragmentation pattern; and

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(c) interpreting the fragmentation pattern obtained to identify the polypeptide;  
wherein said at least one acidic reagent is an N-hydroxysuccinimide ester of the compound of the formula



wherein Y is a spacer which contains aliphatic and/or aromatic fragments and may optionally include additional sulfonic acids.

Claim 2 (original): The method according to claim 1, wherein the acidic reagent has a pKa of less than about 2 when coupled to the polypeptide.

Claim 3 (original): The method according to claim 1, wherein the mass spectrometric technique used in step (b) is matrix-assisted laser desorption ionization (MALDI) mass spectrometry.

Claim 4 (original): The method according to claim 1, wherein the mass spectrometric technique used in step (b) is electrospray ionization (ESI).

Claim 5 (original): The method according to claim 1, wherein in step (c), the fragmentation pattern is interpreted using a software program or database.

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Claim 6 (original): The method according to claim 1, wherein all the steps are conducted as part of an automated or semi-automated procedure.

Claim 8 (currently amended): The method according to claim-7 1, wherein the acidic reagent comprises a 3-sulfopropionic acid N-hydroxysuccinimide ester.

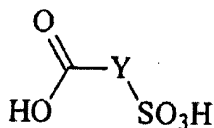
Claim 9 (currently amended): The method according to claim-7 1, wherein the acidic reagent comprises a 2-sulfobenzoic acid N-hydroxysuccinimide ester.

Claim 10 (original): The method according to claim 1, wherein the polypeptide has been obtained by enzymatic digestion.

Claim 11 (original): The method according to claim 10, wherein the enzyme is trypsin.

Claim 12 (original): The method according to claim 1, which further comprises a step of protecting lysine residues prior to the derivatizing step.

2. The following is an examiner's statement of reasons for allowance: The prior art neither teaches nor suggests a method of identifying polypeptide fragmentation patterns wherein at least one acidic reagent is an N-hydroxysuccinimide ester of the compound formula:



wherein Y is a spacer which contains aliphatic and/or aromatic fragments and may optionally include additional sulfonic acids.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis  
Remsen Bldg.  
Room 3D58  
February 1, 2006

  
**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

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The primary examiner has been requested by her supervisor to further evaluate the prosecution of this application upon appeal. Examiner Ceperley called Mr. Ji to discuss the case.

Mr. Ji checked with the inventor(s) who agreed that the term "sulfonyl" in claim 1 should, in fact, be "sulfo"  $\{-\text{SO}_3\text{H}\}$ .

CAPLUS and MARPAT database searches establish that there is prior art to anticipate the compounds of claim 13. Mr. Ji was advised of the following pertinent references: WO 2000/014239; WO 98/03573; WO/95/34595; US 6,426,067; 6,190,650 {see the N-hydroxysuccinimide (NHS) ester of 4-sulfopropionic acid}. In view of the prior art references, "reagent" and "kit" claims 13-20 are not allowable. Note that a "for use in" recitation is not a limitation on the product *per se*. The prior art does not suggest the use of the claimed compounds in a mass spectrometric method for detecting polypeptides.

Consistent with the prior art found and the enablement provided by the specification, Examiner Ceperley will recommend that claim 1 be allowed if amended to change the term "containing a sulfonyl moiety coupled to an ester moiety" to a term which defines the reagent as an N-hydroxysuccinimide ester of the compound of the formula of page 12 of the specification wherein Y is "a spacer which contains aliphatic and/or aromatic fragments and may optionally include additional sulfonic acids". {See for example, the structure **7** of page 28 of the specification.}

Mr. Ji will consult with the inventors and further discuss this case with Mr. Le, the supervisory primary examiner.

  
Mary E. Ceperley

Primary Examiner Art Unit 1641